

STATE OF _____

DEPARTMENT OF _____

CHAPTER 100A-1, ADMINISTRATIVE CODE

CERTIFICATION OF ENVIRONMENTAL TESTING LABORATORIES

100A-1.005 Laboratory Certification Criteria.

(1) A laboratory certified by the Department of _____ pursuant to this rule must comply with the consensus standards adopted at the National Environmental Laboratory Accreditation Conference (NELAC). The NELAC Constitution, Bylaws, and Standards, ____<EPA document number and date for current NELAC Standards>____, is adopted by reference into this rule.

(2) STATE SUPPLEMENTAL CRITERIA:

<This section should include any state requirements for additional analytes and methods that are not required under any EPA programs that are part of NELAC; these requirements must not modify any NELAC Standards (see NELAC 1.8.2 and 6.2.1(d)).>_____

Specific Authority: _____

Law Implemented: _____

History: New _____

100D-1.006 Certification Requirements for Primary Accreditation.

(1) An application for certification shall be made in writing to the Department of _____ on Form _____, accompanied by the application fee listed in Rule 100A-1.017(2). Form _____, "Application for Accreditation of Environmental Testing Laboratories under NELAP," __(revision date)__ is also adopted by reference herein. "NELAP" means the National Environmental Laboratory Accreditation Program, the laboratory certification system derived from laboratories, proficiency test sample providers, and accrediting authorities fulfilling the requirements of the NELAC Standards.

(2) Notwithstanding any other errors or omissions, an application is not completed until the laboratory has fulfilled all of the following requirements:

(a) The application reviewed by the Department of _____ includes the signed certification of compliance by laboratory management.

(b) Proficiency samples are successfully analyzed, if available, from a NELAP-approved proficiency test sample provider, for the requested analytes in the applicable sample matrix in at least two out of the latest three testing rounds attempted.

(c) A written Quality Manual has been prepared to include those NELAC-required elements relevant to the requested fields of testing (test methods and analytes).

(d) An on-site laboratory inspection has been conducted within the last two years for the test methods and analytes for which the laboratory is seeking certification, and any deficiencies noted have been corrected with a remedial action plan and estimated completion date acceptable to the department.

(e) Certification fees are paid as required in Rule 100A-1.017(3).

(f) The laboratory's Technical Director or Directors for the requested fields of testing were found to be qualified according to Section 4.1.1 of the NELAC Standards, referenced in Rule 100A-1.005(1).

(3) Applications for certification not completed within 2 years from the date received by the Department of _____ shall expire, and certification shall be denied.

(4) State Supplemental Certification Requirements:

_____<This section should include any statements about laboratory facilities in noncontiguous premises requiring separate accreditation, plus any mobile laboratory facilities requiring separate accreditation (see NELAC 4.0).>_____

(5) State Scope of Accreditation:

_____ <This section should include any requirements or restrictions on which Fields of Testing will be offered for NELAP accreditation, plus the Fields of Testing under which laboratory technical directors may be exempt from personnel qualification requirements (see NELAC 1.5.2.3.1 and 4.1.1.2.)> _____

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.007 Certification Requirements for Secondary Accreditation.

(1) The Department of _____ shall certify an out-of-state laboratory to perform environmental sample analyses provided that the laboratory complies with all the requirements in this rule.

(2) An out-of-state laboratory shall be eligible for reciprocal certification to perform environmental sample analyses provided:

(a) The laboratory is certified by a state recognized as a NELAP Accrediting Authority for those fields of testing in

which the laboratory is requesting certification pursuant to this rule.

(b) The laboratory submits to the Department of _____ an application on Form _____, which is adopted herein by reference, with a current copy of the laboratory's certification and a listing of the categories, analytes, and test methods certified.

(3) The Department of _____ shall grant certification for those fields of testing after the invoiced certification fees are paid.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.008 Proficiency Testing Requirements.

(1) Laboratories shall bear the cost of any subscription to a proficiency testing program required by the Department of _____ for certification purposes. The Department of _____ shall not be charged a fee for the analysis of any performance evaluation samples.

(2) After the laboratory has submitted its application form or has become certified by the Department of _____

_____, the laboratory must authorize the approved provider, prior to the testing round closing date of subsequent attempts, to submit the proficiency testing results to the Department of _____ concurrently with the submittal of these results to the laboratory. Otherwise, the Department of _____ shall refuse to consider the proficiency test results from that round for fulfilling the requirements of this rule. A laboratory eligible for reciprocal certification pursuant to Section 100A-1.007 of this rule will have fulfilled these requirements for another NELAP-recognized accrediting authority and is thus exempt from the requirements of this subsection.

(3) Proficiency test sample results shall be considered satisfactory when they are within the acceptance limits established by the approved proficiency test sample provider, according to one of the scoring options listed in Chapter 2, Appendix C of the NELAC Standards, which is referenced in Rule 100A-1.005(1).

(4) State Supplemental PT Requirements:

_____<This section should include any statements that require laboratories to do PT samples according to a predefined calendar schedule (see NELAC 2.7.6).>_____

(5) State Supplemental PT Criteria:

_____ <This section should include any statements about
laboratory accreditation status based on passing or failing PT
samples (see NELAC 2.2.4 and
4.1.4(e)).>_____

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.010 On-Site Laboratory Assessments.

(1) The laboratory shall ensure that its documented Quality System, analytical methods, quality control data, proficiency test data, laboratory standard operating procedures, and other records needed to verify compliance with this rule are available for review during the on-site laboratory inspection. The laboratory shall allow the Department's authorized personnel to examine records; observe the laboratory's procedures, facilities, and equipment; and interview staff as necessary to determine such compliance.

(2) The laboratory shall submit to the Department of _____ on Form _____ a Plan of Correction for each deficiency noted during the on-site evaluation. Form _____, "Statement of Deficiencies and Plan of Correction," ____(revision date)___ is herein incorporated by reference.

(3) State Supplemental Requirements:

_____ <This section should include any statements on
requiring on-site laboratory assessments if any change in
ownership or location occurs, frequencies and authorizations
for performing on-site assessments, plus any allowances and
criteria for adding accreditation without an on-site
assessment (see NELAC 4.1.8 and
4.6.2).> _____

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Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.011 Renewal of Annual Certification.

(1) The Department of _____ will renew a
laboratory's certification after return of the renewal
application on Form _____ and receipt of the renewal
certification fee, provided the laboratory is maintaining
compliance with this rule. The Renewal Application, Form
_____, __(revision date)__, and Environmental Testing
Laboratory Renewal Invoice, Form _____, __(revision date)__,
are both herein adopted by reference.

(2) A laboratory's certification shall expire on
__<dates>_____, unless its certification has been renewed.

(3) Failure to receive a renewal invoice does not exempt a laboratory from paying the renewal certification fee.

(4) A laboratory whose certification has expired may reapply for certification in accordance with Rule 100A-1.006(1).

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.012 Display of Certificate.

A current Certificate shall be displayed at all times in a prominent place in each certified laboratory where it may be viewed by the public. Form _____, ____(revision date)____, "NELAP Testing Laboratory Certificate," is adopted by reference herein.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.013 Contractual Agreements, Records, and Reports.

SPECIFIC STATE REPORTING
REQUIREMENTS: _____

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Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.014 Denial or Revocation of Certification.

(1) The Department of _____ is authorized to deny, suspend, limit, or revoke the certification of any laboratory that does not comply with the requirements in the NELAC Standards, referenced in Rule 100A-1.005(1), and this rule.

(2) In determining the denial, revocation, suspension or limitation, the Department of _____ will consider such factors as the gravity of the offense, the danger to the public of the offense, the intent of the violation, the extent of the violation, and the proposed correction of the problem.

(3) The Department of _____ shall take agency action in accordance with __(state regulations)__ and shall afford a person whose substantial interests are affected an opportunity for an administrative hearing in accordance with __(state regulations)__.

(4) The Department of _____ is authorized to issue an emergency order immediately suspending the certification of a laboratory when it determines that any

condition in the certified laboratory presents a clear and present danger to public health and safety.

Specific Authority: _____

Law Implemented: _____

History: New _____

100A-1.017 Fees.

(1) ____(State regulations)____ authorizes the Department of _____ to charge and collect fees for the evaluation and certification of laboratories pursuant to this rule.

(2) A nonrefundable application fee of _____ shall accompany each application. Such fee shall be assessed each subsequent application for additional analytes. The Department of _____ shall not retain this fee in circumstances where the application is not processed.

(3) In addition to the application processing fee, each laboratory shall pay to the Department of _____ the following fees for the initial certification and ____(time period)____ renewal for each category of certification as follows:

_____ (4) The Department of _____ shall assess the expenses it incurs as a result of on-site inspection to the out-of-state laboratories, in addition to the application and certification fees in Subsections (2) and (3) of this section.

Specific Authority: _____

Law Implemented: _____

History: New _____